







BIOSCIENCE DISCOVERY EVALUATION GRANT PROGRAM For Early-Stage Bioscience Company Projects 2009-2010 Program

(RULES AND APPLICATION)

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I. PROGRAM OVERVIEW

The Early-Stage Bioscience Company grants under the Bioscience Discovery Evaluation Grant Program (BDEGP) are intended to spur economic development and help new companies born out of Colorado research institutions to succeed in developing new technologies, business structures, and product development. Grants up to \$250,000 will be accessible to qualified Early-Stage Companies whose technology is licensed from a qualified Research Institution. Grants will support the commercialization of therapeutic or diagnostic products, devices, or instruments to improve human health; bioscience technologies that improve agriculture; or biofuels.

II. APPLICATION AND REVIEW SCHEDULE

OEDIT has established the following application deadline and review/decision schedule:

OEDIT Application	Grant Decisions
Deadline	
First Cycle:	
August 31, 2009	October 15, 2009
Second Cycle:	
January 31, 2010	March 15, 2010

Soft copies of the application must be received by midnight on the deadline date. A hard copy with original signature on the certification page may follow by post.

All funds are available for first cycle applicants; remaining funds will be available in a second cycle. Funds not awarded in these cycles will be available for Early-Stage Company grants in the next fiscal year.

III. STATUTORY AUTHORITY

The Bioscience Discovery Evaluation Grant Program (BDEGP or Program), pursuant to C.R.S. 24-48.5-108 and 12-47.1-701, was established by the Colorado legislature to supply needed resources for improving and accelerating the evaluation process for bioscience research discoveries, to determine the best disposition of these discoveries, and to accelerate viable technologies toward commercialization. The legislature declared that it is in the best interests of the state's economic growth to dedicate financial resources to facilitate the development of new bioscience research discoveries in Colorado and promote Colorado-based bioscience technologies that will ultimately support new bioscience companies and additional primary jobs in Colorado.

IV. ELIGILIBITY

Early-Stage Bioscience Company grants are available to qualified companies that have licensed a technology from an eligible Research Institution (RI) or an Office of Technology Transfer (OTT) for the purpose of accelerating the commercialization of:

- A. Therapeutic or diagnostic products, devices, or instruments to improve human health;
- B. Bioscience technologies that improve agriculture; or
- C. Biofuels

Early-Stage Bioscience Company means a bioscience company that has received less than \$5 million dollars, for the life of the company, from grants and third-party investors at the time of application. Third-party investors are defined as non-founders. The company must employ fewer than twenty people, and must have its headquarters in Colorado.

Research Institution means an institution located and operating in Colorado that is a public or private, nonprofit institution of higher education, a nonprofit teaching hospital, or a private, nonprofit medical and research center. For-profit entities are not eligible for the Program.

Office of Technology Transfer means an office that is affiliated with a research institution and that is charged with the responsibility for technology transfer and that arranges for the sale or licensure of a bioscience research project to an outside entity, which is commonly a commercial enterprise.

Qualified Research Institutions and Offices of Technology Transfer are:

Institution	Office	Contact	Phone	e-mail
Bonfils Blood Center	Technology Transfer	Daniel R. Ambruso, MD	303-341-4000	daniel_ambruso@bonfils.org
Children's Hospital Research Institute	CU Technology Transfer Office	David Allen	303-735-3711	david.allen@cu.edu
Colorado School of Mines	Technology Transfer	Will Vaughan	303-384-2555	will.vaughan@is.mines.edu
	CSU Research Foundation			
Colorado State University	Technology Transfer Office	Carol Clem	970-491-7231	carol.clem@colostate.edu
	Intellectual Property and			
National Jewish Health	Technology Commercialization	Emmanuel Hilaire, Ph. D.	303-398-1262	hilairee@nic.org
University of Colorado (Boulder,				
Colorado Springs, Denver, HSC)	CU Technology Transfer Office	David Allen	303-735-3711	david.allen@cu.edu
University of Colorado Hospital	CU Technology Transfer Office	David Allen	303-735-3711	david.allen@cu.edu
	Intellectual Property and			
University of Denver	Technology Transfer Office	Carley Pavelka	303-871-4230	cpavelka@du.edu
	Graduate School & Technology			
University of Northern Colorado	Transfer	Robbyn R. Wacker, Ph.D.	970-351-1808	robbyn.wacker@unco.edu

Bioscience Research means the study of biological processes, organisms, devices, diagnostics, or systems with the objective of developing products that are intended to improve agriculture, the quality of human life, or the environment. "Bioscience Research" includes, but is not limited to, biofuel research and life sciences research.

Biofuel Research means the use of microorganisms, specialized proteins, or thermal processes to develop biologically based fuel products from plant matter or other biological material, including renewable agricultural sources, and the related processes that make traditional manufacturing of energy cleaner and more efficient.

V. GRANT AWARDS

The Bioscience Discovery Evaluation Cash Fund has been established to hold monies and provide grant awards for the BDEGP. The appropriation is contingent upon the state budget for fiscal year 2009-10. Full program funding would provide \$1,567,500 for Early-Stage Bioscience Company Grants.

A. GRANT MAXIMUM

- 1. Early-Stage Bioscience Company projects can receive a maximum grant of \$250,000.
- 2. The Bioscience Discovery Evaluation Grant Committee (BDEGC) may recommend a grant for an amount other than that requested in the application. Final decisions will be made by the Executive Director of OEDIT.

3. No early-stage company may receive more than \$250,000 in total grants from the BDEGP including all past grants.

B. ELIGIBLE COSTS

- 1. Costs eligible to be paid under the program may only be incurred after the effective date of a legal agreement executed with OEDIT.
- 2. Costs should be related to specific time and effort and are readily and specifically identifiable with the bioscience project. Eligible costs include market analysis, clinical development, regulatory and intellectual property costs, business plans, partnering, investor meetings and associated travel. Proposed costs will be reviewed, and may be approved or denied based on BDEGC recommendations. Final decisions will be made by OEDIT's Executive Director.
- 3. When appropriate, applicants are encouraged to utilize the resources of a qualified business incubator for assistance with structuring and developing their companies. Such costs are eligible for grant funding.
- 4. Documentation of these expenses including invoices of actual expenses shall be maintained.

C. MATCHING FUNDS

Applicants must have matching funds committed at the time of application. At least a 1:1 match of the grant amount requested is required. By project termination, matching funds must be expended on a 1:1 basis. Matching funds must be sourced from other grants or third-party investors; evidence of support from sources outside of the company's principals is an indication of market support for the subject technology and commercialization plan.

D. PAYMENTS

Grant participants shall be reimbursed for eligible costs incurred for performance of the project plan. Payments will be disbursed in accordance with the specific terms and conditions of the project and as outlined in the Grant Agreement.

E. LEGAL AGREEMENTS WITH OEDIT

Grant recipients will need to have an Agreement executed with OEDIT prior to proceeding with any aspect of the bioscience project including the expenditure of state and matching funds.

F. BUDGET ADJUSTMENTS

OEDIT acknowledges that the costs outlined in the Application budget are estimates. Therefore, a Grantee may adjust any budget line-item up to 10% of the total budget without approval from the state. The grantee will need to identify such shifts in its annual project reports. For larger shifts of funds between line-items, the grantee must first seek approval from OEDIT. Please see the sample budget in the Application section for an understanding of the budget layout.

G. RETURN OF UNUSED GRANT MONEY

Upon completion of a bioscience project or within 60 days of early-termination of a project by the Grantee's choice, any advanced and unused grant money shall be returned by the Grantee to OEDIT. The funds will be de-obligated and returned to the Bioscience Discovery Evaluation Cash Fund.

VI. APPLICATION REVIEW

A. STAFF REVIEW

OEDIT will review each application against the rules and statutory requirements outlined in this document.

B. BDEGC

- 1. OEDIT shall convene a Bioscience Discovery Evaluation Grant Committee (BDEGC) comprised of industry experts as well as Colorado Bioscience Association (CBSA) and OEDIT representatives to review, evaluate and make recommendations. All applications will be competitively evaluated by the BDEGC to focus on those that best advance the commercial potential of a bioscience technology. The BDEGC will be interested in the project's potential to strengthen the early-stage bioscience company, attract major capital investment, and to create additional primary jobs in Colorado.
 - i. Basic Evaluation Criteria
 sound scientific basis
 clear market potential
 company competitive advantage
 manageable regulatory path
 capable management team
 use of funds will provide a significant return on investment/advancement of the
 technology
- 2. Applicants will be informed of the BDEGC meeting to consider their proposal, and are encouraged to attend.

VII. CONFIDENTIALITY AND OPEN RECORDS

OEDIT is subject to the Colorado Open Records laws (C.R.S. 24-72-101 through 24-72-112). Thus, documents and other materials received by OEDIT and its employees may be subject to public disclosure.

OEDIT will deny the right of inspection of records considered trade secrets, privileged information, and confidential commercial and financial data. Applicants should clearly mark areas of the application they consider to be trade secrets, privileged information, and confidential commercial and financial data. The entire application may not be marked "confidential". Please note that information considered confidential at the time of application may cease to be so at a later date.

Upon receiving an official open records request, OEDIT will immediately notify the applicant and as needed, seek legal guidance from the Office of the Attorney General for a ruling on confidential information. Applicants should be aware that OEDIT can only respond to requests to review records to the extent that such information is contained in OEDIT's files.

The applicant should also be aware that the BDEGC, most of who are not state employees, will receive and review the application documents. Committee members have agreed to lend their expertise and advice in reviewing grant applications, solely to benefit the public. Panel members agree to treat applications and panel discussions as confidential.

VIII. REPORTING REQUIREMENTS

A. ANNUAL PROGRESS REPORT

- 1. For each project receiving grant funds, the Grantee must submit an annual report documenting the progress of the commercialization activity. OEDIT will provide a report outline for each project based on the objectives, obligations and budget developed for the Statement of Work in the Grant Agreement. The report will need to identify the use of grant and matching funds. Financial documents including receipts, time-sheets, etc. should be attached. OEDIT will provide this outline to the Grantee around February 1, but not later than February 15, each year that the project grant is open. The Grantee must have the report completed and returned to OEDIT by March 15 in the same electronic format that the outline was given. If additional supporting documentation (such as expense receipts) is not available in an electronic format, a hard-copy of the full report and supporting materials may be submitted to OEDIT along with the electronic copy of the report.
- 2. Additionally, OEDIT will request from the OTT from whom the Grantee has licensed the technology, the following information in follow-up reporting on closed or completed projects having received BDEGP grant funds. The follow-up reports will request the following information in order to evaluate the success of the state program in fostering development of Colorado's bioscience industry.
 - a) Status of IP Was new IP developed? Has the IP been extended or obligated outside of the Grantee company? If so, provide details.
 - b) Follow-on Capital Investment Since the conclusion of the state Grant Award, what capital investment has this technology received?

B. PROJECT END REPORT

This report is a similar format to the annual report, but is required at the conclusion of a project/grant. The end report should document completion of all activities outlined in the Statement of Work. This report should include an analysis of the results and findings from the project efforts. Technical difficulties, errors, and planned or recommended next steps should be described. Documentation verifying all project expenditures since the last annual report should be included. An outline for this report will be sent by OEDIT at least one month before the project's end-date. The report will be due to OEDIT within 90 days of the project's end-date, as identified in the formal Grant Agreement.

IX. AUDITS

A. OFFICIAL AUDIT

Each Grantee will be required to provide a copy of their annual business audit to OEDIT, if an audit is completed and released during the term of the Agreement.

B. PROJECT

OEDIT may choose to audit the business activities performed under the Grant Agreement. A grantee shall maintain a complete file of all records, documents, communications, notes and other written materials or electronic media, files or communications, which pertain in any manner to the operation of activities undertaken pursuant to an executed Agreement. Such books and records shall contain documentation of the participant's pertinent activity under a Grant Agreement in a form consistent with good accounting practice.

X. APPLICATION

To be eligible for a grant under the program, a qualified company shall submit to OEDIT one original signed application, and by e-mail a Word or PDF file. Such application shall be submitted on or before the OEDIT Application Deadline in order to be considered in an application cycle. The application should follow this format.

A. IDENTIFYING INFORMATION

- 1. Name of Business and contact information (include contact name, phone #, e-mail address):
- 2. Identify the Business Structure Check the box describing your business structure and Submit the appropriate legal entity structure documentation as applicable:
 - □ Sole Proprietorship
 Filed Trade/Assumed Name Certificate with the Colorado Department of Revenue
 - ☐ General partnership
 General Partnership Agreement (no filing required unless the partnership is also operating under a Trade/Assumed Name if so, follow Sole Proprietorship filing requirements).
 - □ Limited Partnership
 Filed Certificate of Limited Partnership with the Colorado Secretary of State
 - Corporation (C or S)
 Resolution stating who is authorized to incur indebtedness and enter into contracts on behalf of the corporation, filed Articles of Incorporation with the Colorado Secretary of State, and corporate By-Laws
 - □ Limited Liability Company
 Filed Articles of Organization with the Secretary of State
- 3. Name of Office of Technology Transfer (OTT) & Associated Research Institution (RI):
- 4. Has this company or its scientists received any other BDEGP grant? If so, give the BDEGP project name, dates, and award amount.
- 5. Check the box(es) that describe the business' area of bioscience
 - Human Health therapeutic or diagnostic products, devices or instruments
 - □ Agriculture bioscience technologies that improve agriculture
 - □ Biofuels development of biologically based fuels
- 6. Requested Grant Amount (not to exceed \$250,000, excluding matching funds).
- 7. Indicate the number of people employed by the applicant company.
- 8. Attach a Capitalization Report this report will document grant and third-party investor cash injections since the inception of the legal entity. A grant recipient may not have received more than \$5,000,000 from these sources. Do not include founder capital in this report.

A founder is one who pursued the idea or technology as a commercial venture prior to any external money being invested or stock being issued. A third-party investor may include such entities as another company, a venture capital firm, "angel" investors, federal, state or local government, or any combinations of the above. It does not include owners of the small business or their direct family members.

The capitalization criterion is relevant at the time of application. Once a company has been awarded a grant, they may increase their capitalization from third-party sources above the qualifying level.

9.	Has the business	or it	s principal(s)	ever	been	involved	in a	bankruptcy	or	insolvency
	proceedings?									

0	Chapter 7	? No	? Yes	Date	
0	Chapter 11	? No	? Yes	Date	
0	Chapter 12	? No	? Yes	Date	
0	Chapter 13	? No	? Yes	Date	
0	Other	? No	? Yes	Date	

If yes to any of the above, please provide an explanation and a description of the current legal status (use a separate attachment for this item).

- 10. Is the business or its principal(s) involved in any pending lawsuits? If yes, provide a summary.
- 11. Submit Annual Financial Reports/Statements, for the last 3 years or as available.
- 12. Submit projected operations and cash-flow statements outlining the company's financial viability during the term of the project.
- 13. Provide a summary of the license agreement for the subject technology with a qualified research institution or OTT. Include a name or description of the licensed technology, license type, parties involved, and financial terms. *Note: OEDIT will require the RI or OTT to verify this information*.
- 14. Submit a letter of support from the OTT, including any recommended terms or conditions for consideration by the BDEGC.
- 15. Include a signed W-9 form.
- 16. Include a Certificate of Good Standing from the CO Secretary of State.
- 17. Include a board resolution or company bylaws that identifying the individual(s) authorized to enter into contracts on behalf of the grantee company (please, highlight such information).
- 18. If applicant is a sole-proprietor, or any individual has greater than 20% ownership if the company, complete a Credit Investigation form.

B. PROJECT NARRATIVE

- 1. Summary (1 page or less in layman's terms, do not include any confidential information) Provide a brief summary of the proposed project, including a description of the commercialization plan, and any scientific research and its merits. Describe the current stage of commercialization for the subject technology, along with its anticipated commercial potential. Identify the market segment that the developed technology will address. Will this product/service be a new offering? Does it improve upon existing offerings? Will it partner with existing products/services?
- 2. Project Plan (3 pages or less in layman's terms)
 - a) Describe the specific objectives of the project in 70 words or less. (*if approved, this language will become the general description in a Statement of Work*)., and explain how this project will enhance the commercialization of the subject research or technology.
 - b) Explain how the project or its outcomes will positively impact human health, agriculture, or the biofuels industry. What market need is being addressed?
 - c) Describe how the proposed project builds upon previous work that has been conducted by the applicant and other institutions worldwide.
 - d) Identify problems that you might encounter in the proposed project and how you intend to manage and/or resolve them.

- e) Identify any prior or current grants the applicant has to develop this technology, and explain plans for future grants or other financing for the subject technology.
- f) Describe how the accomplishment of project goals/milestones will advance the commercialization effort and the company.
- 3. Commercialization Strategy (2 pages or less in layman's terms)
 - a) Explain the market potential for the product or service.
 - b) Based on the company's stage of development, describe the commercial roadmap (is this an established pathway or must a new model be invented), the product model, business model, revenue model. Provide summary descriptions of comparable products and companies.
 - c) Describe the commercialization spectrum (from infancy to sales) explaining where the technology is today, and how far along the spectrum it will progress by completing the work you plan to undertake with the state grant and matching funds.
 - d) Identify any developed intellectual property to-date on this technology or project.
 - e) Specify capital needs, sources, and long-term milestones beyond the proposed project.
 - f) Estimate the long-term outcomes of this project in terms of Colorado jobs and investment.

4. Hazardous Substances

Will project work involve hazardous substances or activities? If so, what precautions are being taken. Note laws that apply, additional insurance, etc.

C. WORK PLAN

Drawing on the Project Narrative, identify project tasks and milestones on a timeline. *Please be concise as these will become the "Obligations" in a Statement of Work.* Make sure to identify project start and end dates in terms of months from an executed Grant Agreement. Be aware that it will take approximately 1.5 months following the grant decision date to process follow-on information and execute a grant agreement.

D. BUDGET

- 1. Has the subject technology of this application received other grant funding, including an SBIR or STTR? If so, please provide grant source, amount, and scope of grant project.
- 2. Provide evidence of the grant match in the form of a commitment letter, grant award notification, verification of deposit, or other document as approved by OEDIT.
- 3. Provide a project budget that supports the Work Plan above. Refer to the Eligible Cost information in the Grant Awards section of this document. The budget should include all anticipated project costs and identify Program grant and matching funds. Matching funds must meet or exceed the amount of grant funds requested.

This sample budget outline is provided for direction. Please include a reasonable level of detail for planned project expenditures. Matching funds may be applied to different lineitems than BDEGP funds, but should develop the same technology and be spent over the same time period.

Line Item	Sou	<u>Total</u>	
Project Costs	BDEGP	Match	
Project Management	2,500	2,500	5,000
Incubator Advisory Costs	3,250	3,250	6,500
Clinical Trial Protocol	12,500	12,500	25,000
Regulatory Approval Plan	10,000	10,000	20,000
Market Analysis	4,000	4,000	8,000
IP Assessment & Strategy	12,000	12,000	24,000
Investor Meetings	2,500	2,500	5,000
TOTAL	\$46,750	\$46,750	\$93,500

E. MANAGEMENT TEAM'S BIOGRAPHICAL INFORMATION

Attach curriculum vitae or a short narrative with relevant background and accomplishments for each of the management team and key investigators. Specify relevant company, advisor, and management team capabilities and expertise to execute a business plan.

CERTIFICATIONS

I certify that:

- The bioscience project described in this application and for which the company is requesting Program funds complies with the statutory criteria, rules and application requirements identified in this application document:
 - o the project involves the use of biological processes, organisms, devices, diagnostics, or systems with the objective of developing products that are intended to improve agriculture, the quality of human life, or the environment;
 - o the scope of the project is the scope required to enhance the commercialization of the technology in Colorado;
- The applicant has a dedicated, matching source of moneys that is equal to or greater than the amount applied for under the Program.
- The information contained in this Application, including all attachments and exhibits, are true and correct.
- The applicant company is headquartered in Colorado. Headquartered is defined as the chief location of a business from which its policies are made and orders are issued.
- The person's or persons' signature on these Certifications and Application are authorized to act on behalf of the applicant company.
- The applicant company complies with the insurance requirements required for state contracts as stated in the Insurance Requirement Attachment.

Name and Title	Company Legal Name
Signature	Date